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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MADISON JOINT VENTURE LLC, *Plaintiff,* v. CHEMO RESEARCH S.L., EXELTIS USA, INC., and SERGIO SOSA-ESTANI, *Defendants.*	Case No. 2:19-cv-8012-JMV-SCM

MEMORANDUM OF LAW IN SUPPORT OF SAVANT NEGLECTED DISEASES LLC'S MOTION TO INTERVENE AND FOR A STAY

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I.

INTRODUCTION

Savant Neglected Diseases LLC ("Savant") respectfully moves to intervene and for a stay pending the outcome of *Humanigen, Inc., et al. v. Savant Neglected Diseases, LLC* (the "Delaware Litigation"), a related case in Delaware currently set for trial on April 12, 2021. The Delaware Litigation will determine whether Savant or current Plaintiff Madison Joint Venture ("Madison") is the rightful owner of the property and legal claims at the heart of this matter—in other words, which of them has standing to prosecute *this case*.

Savant is the architect of the effort to obtain FDA approval for benznidazole. In 2013, it exclusively licensed the rights to the leading study on benznidazole's efficacy for treating Chagas disease. Subsequently, Savant contributed those rights to a joint development project with Humanigen, Inc. ("Humanigen"), which co-owns Plaintiff Madison Joint Venture LLC ("Madison"). In exchange for this critical data, Savant was promised $21 million in Milestone Payments, 20% of the proceeds from the sale of a valuable priority review voucher, and 15% of the actual sales of benznidazole. Defendant Chemo Research, S.L. ("Chemo") and its affiliates later misappropriated this data and used it to obtain FDA approval for benznidazole first.

Due to Humanigen's material breaches of the joint development agreement, Savant owns the right to sue the Defendants here. That is the core subject of the Delaware Litigation. And even if Savant does not prevail on its breach of contract claim, the Delaware Litigation will confirm how much Savant must receive out any recovery here.

Savant's intervention motion satisfies the elements of both permissive and by-right intervention under FRCP 24: it is timely, it protects Savant's interests that would otherwise be jeopardized, and it conserves judicial and party resources. Indeed, if Madison and the Defendants

here are found not to own the rights they claim to own in this lawsuit, they will have been locked in a quixotic battle for nothing—one which would have to be restarted. Allowing the Delaware Litigation to conclude will ensure that the correct plaintiff is prosecuting this case, thereby simplifying the issues and avoiding significant wasted effort for the Court.

II.

FACTUAL AND PROCEDURAL BACKGROUND

Given the prior submissions in this case, we assume the Court's familiarity with the general background of this dispute. The relevant facts related to Savant's motion are summarized below. A full recitation of the facts is contained in Savant's proposed complaint and its operative pleading in the Delaware Litigation.[1] (Declaration of Megan Dubatowka, dated October 9, 2020 ("Dubatowka Decl."), ¶¶ 3-4, Exs. 1, 2.)

Savant Begins the Benznidazole Development Program and Obtains Exclusive Rights to the Sosa-Estani Study, which is Key to Securing FDA Approval of the Drug.

Savant was co-founded in 2009 by Stephen Hurst, its President and CEO, and by Scott Freeman, its Chief Medical Officer. Savant's focus was on researching, developing, and bringing to market pharmaceuticals in areas with significant unmet medical needs that were being ignored by major pharmaceutical companies. (Dubatowka Decl. Ex. 2, ¶ 19.)

At the end of 2011, Savant began to evaluate the potential for a benznidazole as a treatment for Chagas disease, a tropical parasitic infection that primarily affects individuals in rural parts of

[1] The Delaware Litigation is styled in full as *Humanigen, Inc., et al. v. Savant Neglected Diseases, LLC*, C.A. No. N17C-07-068 PRW CCLD (Del. Sup. Ct.). The facts set forth herein are based on Savant's operative complaint in the Delaware Litigation. Given the reason for Savant's proposed intervention, any complaint it ultimately files here will likely change after the Delaware Litigation ends. Nevertheless, to comply with Fed. R. Civ. P. 24(c), Savant has attached a proposed draft complaint as Exhibit 1 to the Dubatowka Declaration.

Latin America. While benznidazole had already been approved for the treatment of Chagas disease in Argentina and Brazil, it was not commercially available in the United States or in many other countries where Chagas affects rural populations. (*Id.*, ¶¶ 20-25.)

Savant learned of a double-blind, randomized trial on the pediatric use of benznidazole for Chagas disease conducted in 1998 by Dr. Sergio Sosa-Estani (the "Sosa-Estani Study"). This study was the leading trial supporting benznidazole's efficacy in treating Chagas; Savant learned from the FDA in 2012 that the Sosa-Estani Study would be critical in gaining approval for the drug.

Thus, in late 2013, Savant entered into a license agreement with the Instituto de Efectividad Clínica y Sanitaria ("IECS"), an Argentinean academic institution with ties to Sosa-Estani, that granted Savant an exclusive, perpetual and irrevocable license to the Sosa-Estani Study and its underlying data. (*Id.*, ¶¶ 31-35.)

Savant Partners with Humanigen in a Joint Benznidazole Development Program.

Savant began refining its version of benznidazole to prepare for a potential FDA application. During this period, Savant approached Chemo Group, a large multinational pharmaceutical drug company that is the corporate parent of Defendants Chemo and Exeltis, and the Drugs for Neglected Diseases Initiative ("DNDi"), a non-profit, about working together to gain FDA approval for benznidazole. Both said they were not interested.

In August 2015, the FDA added Chagas to the list of neglected tropical diseases that were eligible for a "priority review voucher." This voucher would entitle a pharmaceutical company that obtained FDA approval for a drug to treat a listed disease to thereafter expedite the FDA approval process for any other drug. Critically, priority review vouchers are transferrable, and in recent years, have sold for as much as $350 million. (*Id.*, ¶ 37.)

Savant's exclusive rights to the Sosa-Estani Study made it a much more attractive business partner, since it was in the lead position to obtain FDA approval of benznidazole, and thus receive a voucher. It soon entered into the Agreement for the Manufacture, Development and Commercialization of Benznidazole for Human Use (the "MDC Agreement") with Humanigen, then known as KaloBios Pharmaceuticals, which was emerging from bankruptcy. The MDC Agreement required Savant to provide Humanigen with its exclusive access to the Sosa-Estani Study and to Dr. Sosa-Estani himself, and for Humanigen to fund and otherwise take all necessary and reasonable steps to obtain FDA approval for benznidazole. Humanigen was required to pay Savant $21 million in "Milestone Payments" while commercializing the drug, plus 20% of the proceeds from any voucher they obtained and 15% of all Humanigen's sales of benznidazole. (*Id.*, ¶¶ 49-51.)

From the beginning, Humanigen also knew it was in a race to get FDA approval for benznidazole. Before the parties executed the development contract, Humanigen had information suggesting that Chemo Group had also decided to seek approval for the drug so as to win the valuable priority review voucher. This was a risk that Humanigen knowingly accepted. Under the terms of the contract, Humanigen was obligated to commercialize benznidazole irrespective of whether a FDA priority review voucher was still available, as the voucher represented only one source of potential revenue from the drug. In order to maximize the value of the contract and Savant's exclusive data, Humanigen had to move quickly because only the company that received FDA approval for benznidazole first would receive the priority review voucher. (*Id.*, ¶¶ 4, 38-48.)

Chemo Misappropriates Savant's Data and Obtains the Valuable Priority Review Voucher.

As set forth in Savant's proposed complaint, in or around February 2016, Chemo Group entered into an agreement with DNDi to seek FDA approval for benznidazole. Chemo Group

committed to using its resources to manufacture and distribute the drug through its subsidiaries, Defendants Chemo and Exeltis, and DNDi agreed to procure data to support its effectiveness as part of its commitment to this so-called "alliance." Chemo and DNDi agreed to split the sale proceeds of the voucher evenly between them.

Publicly available FDA documents and other information have revealed just how this corrupt bargain was carried out. Seemingly at Chemo's direction and with its knowledge, DNDi promised Chagas disease researchers and research institutions (like Sosa-Estani and IECS) lucrative research grants if they would provide access to the benznidazole data. DNDi also hired Sosa-Estani, at that time a government employee, as head of its Chagas disease initiative. Sosa-Estani then provided Savant's data to Chemo and Exeltis for use in their application. In other words, Defendants seemingly directed a bribe to a public official to obtain access to information he had no right to give them.

On August 29, 2017, the FDA announced that Chemo had received FDA approval for its competing version of benznidazole and awarded it the priority review voucher. (*Id.*, ¶ 66.) Humanigen then mothballed its drug development program, claiming that without the voucher its investment in benznidazole was uneconomical. This was in breach of the MDC Agreement, which required Humanigen either (1) to continue with its drug development efforts (both in the United States and abroad), or (2) to offer to return Savant's exclusive license to it in exchange for payment of 90% of Humanigen's drug development costs. (*Id.*, ¶¶ 7, 51-54, 89.)

Humanigen's Putative Assignment to Madison

By this point, Humanigen was in dire economic straits and owed substantial sums to a consortium of creditors. Rather than resort to bankruptcy once more (which would have given Savant a seat at the creditors' table), Humanigen terminated its drug development program and

sold the assets for debt relief. On December 21, 2017, Humanigen and its primary creditors executed a Securities Purchase and Loan Satisfaction Agreement (the "SPL Agreement"). In it, Humanigen agreed to transfer its interests in benznidazole and all related legal claims to an entity it would create with its major creditor; this entity became Plaintiff Madison. (*Id.*, ¶ 71.)

Litigation Begins and Savant is Cut Out of Recovery Efforts.

Litigation first began between Savant and Humanigen shortly before Chemo obtained the voucher. Humanigen launched the first iteration of the Delaware Litigation on July 10, 2017 in state Superior Court, alleging that Savant owed it several million dollars for cost overruns associated with the development program. Savant responded with claims that Humanigen owed it at least $2 million in milestone payments under the MDC Agreement. (*Id.*, ¶¶ 63-64.)

Nearly two years later, on March 6, 2019, Madison commenced this lawsuit against Chemo, Chemo's U.S. affiliate, Exeltis USA, Inc., and Dr. Sergio Sosa-Estani (collectively, the "Chemo Defendants"). Madison alleges that Savant exclusively licensed certain data from Dr. Sosa-Estani for purposes of obtaining FDA approval of benznidazole and assigned that license to Humanigen for purposes of completing drug development, and that Humanigen later assigned all claims related to Chemo's misappropriation of this data to Madison. Madison asserts that but-for the Chemo Defendants' misappropriation of Savant's proprietary data, Humanigen would have received FDA approval for benznidazole. (*Id.*, ¶¶ 9, 87.)

Madison has alleged that it alone is entitled to hundreds of millions in resulting damages. Madison thus seeks to recover all of the benefits that would have flowed to both Humanigen and Savant in the but-for world in which Humanigen was successful in receiving FDA approval. This was further confirmed when Madison's attorneys communicated to Savant, in unequivocal terms, that they did not intend to disburse any recovery to Savant from the resulting litigation. (*Id.*, ¶ 104.)

Savant Asserts Claims in Delaware to Protect Its Rights.

Shortly after Madison filed this case, Savant took action to protect its right to assert the claims that Madison argues belong solely to it. Savant filed a new action, which was subsequently consolidated in the existing Delaware Litigation, alleging that Humanigen materially breached the MDC Agreement by, among other things: (1) failing to make required Milestone Payments to Savant; (2) unilaterally shutting down the development program, thereby abandoning its performance obligations; and (3) orchestrating a scheme with Madison to launch this lawsuit in New Jersey and cut Savant out of any recovery. These material breaches mean that the rights Madison claims to own here long ago reverted to Savant. Savant further alleged that the creation of Madison was a fraudulent transfer that was designed to frustrate Savant's rights.

On August 17, 2020, the Delaware court decided competing motions to dismiss, as well as Savant's motion for summary judgment on the issue of champerty. It declined to dismiss any of Savant's claims, holding that "[i]f proven at trial, [Humanigen's] acts breach a variety of obligations the MDC creates leading directly to Savant's injury." (Dubatowka Decl. Ex. 4, at 10.) Likewise, apparently to avoid a finding that the assignment of the MDC Agreement to Madison was champertous, the Delaware court found that Humanigen "assign[ed] the MDC *in toto* to Madison." (*Id.*, at 18). Because Madison assumed both Humanigen's assets and liabilities under the MDC Agreement—including Humanigen's obligations to make the Milestone Payments and to pay Savant its portion from the sales of the voucher and benznidazole—Madison is responsible for compensating Savant in the event of any monetary recovery here. (*Id.*, at 20 (explaining that the "Madison Operating Agreement appears to contemplate the MDC not as a contract for a mutual exchange of promises, but as a bundle of litigation actions for money damages eventually to become a simple net judgment.").) Accordingly, even if Savant is unable to

demonstrate at trial that Humanigen breached the MDC Agreement, which would trigger a reversion of the assets exchanged under the contract, Savant would still be entitled to its rightful allocation of any "simple net judgment" against the Chemo Defendants.

On September 30, 2020, the Delaware court entered a case management order with a five-day trial set to commence on April 12, 2021. (Dubatowka Decl. Ex. 3, at 3.) Prior to filing this motion, counsel for Savant contacted each of the parties (with the exception of Dr. Sosa-Estani) here for their position on this motion. Chemo's counsel indicated that they would consent to intervention and agreed that this case should be stayed (albeit for different reasons), and said they are likely to file their own stay motion. Madison objects to this motion in its entirety.

III.

ARGUMENT

Rule 24 envisions two types of intervention: intervention as a matter of right under Rule 24(a)(2), and permissive intervention under Rule 24(b)(1). As set forth below, Savant satisfies the criteria for both. However, because permissive intervention would plainly be justified if the Court determines that a stay of this action is appropriate, the propriety of a stay is the primary issue to be decided.

A. This Case Should Be Stayed Pending the Outcome of the Delaware Litigation.

Savant's reason for intervening is to seek a stay of these proceedings pending the outcome of the Delaware Litigation, which will resolve the basic question of who between Savant and Humanigen actually owns the claims Madison has asserted here against the Chemo Defendants. This Court has "broad power to stay proceedings." *Bechtel Corp. v. Local 215 Laborers' Int'l Union of N. Am.*, 544 F.2d 1207, 1215 (3d Cir. 1976). The textbook example of an appropriate stay is where "a court . . . hold[s] one lawsuit in abeyance to abide the outcome of another which

may substantially affect it or be dispositive of the issues." *Id.* When considering a stay, this Court should weigh "whether a stay will simplify issues and promote judicial economy, the balance of harm to the parties, and the length of the stay." *Bais Yaakov of Spring Valley v. Peterson's Nelnet, LLC*, 2011 WL 4056318, at *2 (D.N.J. Sept. 12, 2011). All three criteria are met here.

Allowing the Delaware Litigation to conclude before moving this case forward will promote judicial economy because it will avoid having to reinvent (or at least relitigate) the wheel if Madison is found to lack standing to prosecute its claims. *See Novartis AG v. HEC Pharm Co., Ltd.*, 2015 WL 5440821, at *2 (D.N.J. Sept. 14, 2015) (staying New Jersey litigation in favor of ongoing Delaware action because "it is plainly contrary to judicial economy, time, and energy for the same parties to litigate the same patent in two different district courts before two different District Judges."). To put it another way, "[g]ranting a stay would avoid the possibility of dissipating both the Court's and the parties' resources in litigating a claim that [a related] case could eventually render moot." *Ohio Willow Wood Co. v. Alps S., LLC*, 2014 WL 12656913, at *4 (S.D. Ohio Feb. 18, 2014); *see also id.,* at *3 ("A stay would similarly produce a consistent fact-finding, which would promote trial efficiency, as well as a consistent outcome between two cases with at least partially overlapping patterns of material fact."); *Glenbrook Estates, Inc. v. Wausau Ins. Companies*, 2007 WL 4259993, at *5-6 (D.N.J. Nov. 30, 2007) (staying federal declaratory judgment action in favor of ongoing state case where "discovery . . . may substantially aid [the federal court] in determining the outcome of [the federal case] at a later, more appropriate time.").

Next, a stay would be beneficial to all involved. This case is only in its infancy, as the Chemo Defendants' motion to dismiss has not been decided and no fact discovery has taken place. It makes no sense for Madison and the Chemo Defendants to spend time and resources litigating when there may be no cognizable basis for a lawsuit between them. Conversely, denying the stay

would significantly prejudice Savant because its ability to be made whole could be jeopardized. For example, if Madison settles this case before there is a decision in Delaware as to the ownership of any recovered assets, it is well-positioned to cut Savant out of the deal. Madison is an empty shell controlled by Nomis Bay Ltd., a Bermuda-based entity that an investor, Marc Bistricer, has utilized for his Humanigen investments.[2] Neither of them have ties that would prevent the dissipation of assets that rightfully belong to Savant. Moreover, Humanigen and Nomis Bay have already shown a disregard for Savant's rights—they avoided putting Humanigen into bankruptcy, which would have afforded Savant protection as a creditor, and instead cut an under-the-table deal to try to place the benznidazole assets in Madison's name alone. Regardless of the outcome of this motion, the Court should view any purported settlement that does not include Savant with a high degree of skepticism.

Finally, the length of the requested stay is reasonable. The trial in Delaware is currently scheduled to begin on April 12, 2021. Assuming this motion is fully briefed by mid-November, and that there is a verdict by mid-May 2021, this would result in a stay of only six months. This minor delay will not unduly prejudice Madison, particularly given the nascent state of the litigation. *See Advanced Dynamic Interfaces, L.L.C. v. Aderas Inc.*, 2013 WL 6989428, at *1 (D. Del. Jan. 11, 2013) (granting a motion to intervene and for a stay where "the court has not yet held a scheduling conference in this matter, a trial date has not been set, and discovery has not yet commenced."); *Honeywell Int'l Inc. v. Audiovox Commc'ns Corp.*, 2005 WL 2465898, at *4 (D. Del. May 18, 2005) (same).

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[2] Mr. Bistricer's sharp business practices are detailed in a pair of articles attached as Exhibit 5 to the Dubatowka Declaration.

B. Savant Satisfies the Criteria for Intervention.

i. Intervention is Proper as a Matter of Right Under Rule 24(a)(2).

The Third Circuit has "interpreted Rule 24(a)(2) to require proof of four elements from the applicant seeking intervention as of right: first, a timely application for leave to intervene; second, a sufficient interest in the litigation; third, a threat that the interest will be impaired or affected, as a practical matter, by the disposition of the action; and fourth, inadequate representation of the prospective intervenor's interest by existing parties to the litigation." *Kleissler v. United States Forest Serv.*, 157 F.3d 964, 969 (3d Cir. 1998); *see U.S. v. W. Sur. Co.*, 2016 WL 1030392, at *3 (D.N.J. Mar. 15, 2016) (explaining that the intervention inquiry should be focused on whether the intervenor's interests "diverge" from those of the existing plaintiff).

First, Savant's motion is timely because it is being filed before fact discovery has even begun in this action, and less than two weeks after the Delaware court entered a case management order setting a trial date of April 12, 2021. Dubatowka Decl., ¶ 5, Ex. 3; *see Mountain Top Condo. Ass'n v. Dave Stabbert Master Builder, Inc.,* 72 F.3d 361, 370 (3d Cir. 1995) (holding that a motion to intervene was timely, despite being filed four years after litigation commenced, when it was filed during the mediation stage but before extensive discovery or depositions were conducted).

Second, Savant plainly has significant interests in this litigation. Savant intends to prove in the Delaware Litigation that it alone has the right to sue Chemo. Such a finding would make it, not Madison, the proper plaintiff here. Courts have found an interest sufficient to justify intervention where the proposed intervenor was allegedly the legal owner of the intellectual property at the center of the underlying dispute. *See, e.g., Endoheart AG v. Edwards Lifesciences Corp.*, 2015 WL 6956603, at *3 (D. Del. Nov. 6, 2015) (alleged genuine owner of a patent had a cognizable interest in a patent infringement case), *report and recommendation adopted*, 2016 WL 1317203 (D. Del.

Mar. 31, 2016); *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 223 F.R.D. 326, 329 (D.N.J. 2004) (same).

Even if Savant does not win a complete victory in Delaware, it still retains a substantial interest in this litigation because Madison could "impai[r] or affec[t]" Savant's rights unless Savant is afforded the chance to protect them. *Honeywell*, 2005 WL 2465898, at *4. For example, if the trial confirms Savant has the right to share in some, but not all, of Madison's recovery here, Madison would have a strong incentive to prioritize claims for which it could keep a greater overall recovery, and minimize those that would more benefit Savant (*e.g.*, future benznidazole profits). *See Princeton Biochemicals*, 223 F.R.D. at 329 (absent intervention, the alleged owner of the infringed property "will be deprived of the full benefits of owning the 172 patent").

Third, Madison cannot and will not adequately protect Savant's interest here. The burden to show that a current plaintiff is not an adequate representative is minimal. *See Brody By and Through Sugzdinis v. Spang*, 957 F.2d 1108, 1123 (3d Cir. 1992) (citing *Hoots v. Pennsylvania*, 672 F.2d 1133, 1135 (3d Cir. 1982)). "Representation will be considered inadequate on any of the following three grounds: (1) that although the applicant's interests are similar to those of a party, they diverge sufficiently that the existing party cannot devote proper attention to the applicant's interests; (2) that there is collusion between the representative party and the opposing party; or (3) that the representative party is not diligently prosecuting the suit." *Id.*

Savant easily satisfies these standards. Madison is adverse to Savant in the Delaware Litigation, and has acted to frustrate Savant's rights at every turn. Madison and Savant disagree as to who owns the rights to the claims at issue in the underlying litigation, who may recover against Chemo and the other Defendants, and whether Savant is entitled to any recovery whatsoever.

Accordingly, Savant is entitled to intervene as of right under Rule 24(a)(2).

ii. In the Alternative, The Court Should Permit Savant to Intervene.

Alternatively, Rule 24(b) allows the Court to permit "anyone to intervene who," as is relevant here, "has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1)(B). A party seeking to permissively intervene must establish that "(1) the motion is timely; (2) [their] claim or defense and the main action have a question of law or fact in common; and (3) the intervention may not cause undue delay or prejudice to the original parties' rights." *Cole v. NIBCO, Inc.*, 2016 WL 1313106, at *6 (D.N.J. April 4, 2016) (internal citations omitted). "Whether to allow a party to permissively intervene is left to the sound discretion of the Court." *Id.*

As set forth above, the first two prongs of this standard are readily met. Savant's application is timely, and there is significant overlap between its claims and Madison's claims regarding issues of law and fact. Further, as described above, Savant's intervention would not cause any undue prejudice, and Madison's short-term inconvenience at having its litigation stayed would be outweighed by its, Defendants', and the Court's interest in litigating with the correct parties. Conversely, if Savant was not allowed to intervene, it would be required to file a separate action to enforce its rights following the conclusion of the Delaware Litigaiton, thereby wasting judicial resources and forcing all parties to this litigation back to the courthouse unnecessarily.

III.

CONCLUSION

For the foregoing reasons, Savant Neglected Diseases, LLC should be permitted to intervene and this case should be stayed pending the outcome of the Delaware Litigation.

DATED: October 9, 2020
New York, NY

Respectfully submitted:

/s/ Megan Dubatowka

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